

UNITED STATES DISTRICT COURT  
FOR THE WESTERN DISTRICT OF TENNESSEE

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MELISSA MITCHELL,	)
	)
	)
<i>Plaintiff,</i>	)
	)
v.	)
	)
ELI LILLY AND COMPANY, and	)
BOEHRINGER INGELHEIM	)
PHARMACEUTICALS, INC.,	)
	)
<i>Defendants.</i>	)

No. 16-cv-02384-JDB

**JURY TRIAL DEMANDED**

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**DEFENDANT BOEHRINGER INGELHEIM PHARMACEUTICALS, INC.’S  
ANSWER TO PLAINTIFF’S SECOND AMENDED COMPLAINT**

Defendant Boehringer Ingelheim Pharmaceuticals, Inc. (“BIP”) by and through its undersigned counsel, hereby answers Plaintiff’s Second Amended Complaint (“Am. Compl.” or “SAC”). BIP specifically denies each and every allegation of the SAC not otherwise expressly admitted, qualified, or denied in this Answer. BIP states that it is answering Plaintiff’s allegations only on behalf of itself, even where Plaintiff’s allegations refer to alleged conduct by other entities. BIP expressly reserves the right to seek to amend and/or supplement this answer as may be necessary.

**Introduction**

1. BIP admits that it holds the patent and new drug application (“NDA”) for Jardiance and markets and sells Jardiance, in accordance with Jardiance’s U.S. Food and Drug Administration (“FDA”)-approved labeling. Due to the vagueness and ambiguity of the remaining allegations contained in paragraph 1 of the SAC, BIP is without knowledge or information sufficient to form a belief as to the truth of such allegations, and, on that basis, BIP denies such allegations.

2. BAPI denies the allegations contained in paragraph 2 of the SAC.

3. BAPI denies the allegations contained in paragraph 3 of the SAC.

4. BAPI is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 4 of the SAC related to Plaintiff's alleged medical history, and, on that basis, BAPI denies such allegations. BAPI denies that BAPI and/or Jardiance have in any way caused or contributed to Plaintiffs' alleged injuries or damages, if any.

5. To the extent the allegations contained in paragraph 5 attempt to summarize the claims raised in this action, no response is required. To the extent a response is required, BAPI denies that BAPI and/or Jardiance have in any way caused or contributed to Plaintiffs' alleged injuries or damages, if any, and denies that Plaintiffs are entitled to any of the damages or relief sought against BAPI.

6. To the extent the allegations contained in paragraph 6 attempt to summarize the claims raised in this action, no response is required. To the extent a response is required, BAPI denies that BAPI and/or Jardiance have in any way caused or contributed to Plaintiff's alleged injuries or damages, if any, and denies that Plaintiff is entitled to any of the damages or relief sought against BAPI. BAPI lacks knowledge or information sufficient to form a belief as to the truth of the allegations related to Plaintiff's alleged use of Jardiance and to Plaintiff's alleged medical history, and, therefore, denies such allegations.

#### **PARTIES**

7. BAPI is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 7 of the SAC, and, on that basis, BAPI denies such allegations. BAPI denies that BAPI and/or Jardiance have in any way caused or contributed to

Plaintiff's alleged injuries or damages, if any, and denies that Plaintiff is entitled to any of the damages or relief sought against BIPI.

8. BIPI admits that it is a Delaware corporation with its principal place of business in Ridgefield, CT, that it holds the patent and new drug application ("NDA") for Jardiance, and that it markets and sells Jardiance, in accordance with Jardiance's FDA-approved labeling. Due to the vagueness and ambiguity of the remaining allegations contained in paragraph 8 of the SAC, BIPI is without knowledge or information sufficient to form a belief as to the truth of such allegations, and, on that basis, BIPI denies such allegations.

#### **JURISDICTION AND VENUE**

9. The allegations contained in paragraph 9 of the SAC state legal conclusions to which no response is required. To the extent a response is deemed necessary, BIPI admits that complete diversity of citizenship exists between Plaintiff and BIPI as the allegations in the SAC currently stand, and BIPI admits that Plaintiff claims damages exceeding \$75,000, but denies all allegations of liability directed toward it and further denies that Plaintiff is entitled to any damages.

10. BIPI admits that, at certain times not specified in the SAC, BIPI has lawfully conducted business in the State of Tennessee. Due to the vagueness and ambiguity of the remaining allegations contained in paragraph 10 of the SAC, BIPI is without knowledge or information sufficient to form a belief as to the truth of such allegations, and, on that basis, BIPI denies such allegations.

11. BIPI denies the allegations contained in paragraph 11 of the SAC.

12. BIPI admits that, at certain times not specified in the SAC, BIPI has lawfully conducted business in the State of Tennessee. Due to the vagueness and ambiguity of the

remaining allegations contained in paragraph 12 of the SAC, BIPI is without knowledge or information sufficient to form a belief as to the truth of such allegations, and, on that basis, BIPI denies such allegations.

13. The allegations contained in paragraph 13 of the SAC state legal conclusions to which no response is required. To the extent a response is deemed necessary, BIPI is without knowledge or information sufficient to form a belief as to the truth of such allegations, and, on that basis, denies the allegations contained in paragraph 13.

14. **ANSWER:** The allegations contained in paragraph 14 of the SAC state legal conclusions to which no response is required. To the extent a response is deemed necessary, BIPI is without knowledge or information sufficient to form a belief as to the truth of such allegations, and, on that basis, denies the allegations in paragraph 14.

#### **FACTUAL BACKGROUND**

15. BIPI admits that, on August 1, 2014, the FDA determined Jardiance to be safe and effective for use “as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus” and that Jardiance is member of the gliflozin drug class referred to as SGLT2 (Sodium Glucose Cotransporter 2) inhibitors. BIPI denies the remaining allegations contained in paragraph 15 of the SAC.

16. To the extent the allegations contained in paragraph 16 of the SAC relate to products other than Jardiance, BIPI is without knowledge or information sufficient to form a belief as to the truth of such allegations, and, on that basis, BIPI denies such allegations. To the extent that the allegations contained in paragraph 16 of the SAC relate to Jardiance, BIPI admits that, on August 1, 2014, the FDA determined Jardiance to be safe and effective for use “as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus,”

as indicated in the FDA-approved labeling for Jardiance. BIPI denies the remaining allegations contained in paragraph 16 of the SAC.

17. To the extent the allegations contained in paragraph 17 of the SAC relate to products other than Jardiance, BIPI is without knowledge or information sufficient to form a belief as to the truth of such allegations, and, on that basis, BIPI denies such allegations. To the extent that the allegations contained in paragraph 17 of the SAC relate to Jardiance, BIPI states that the mechanism of action outlined in the Jardiance product labeling operative at the time of Plaintiff's alleged injury speaks for itself and, on that basis, denies the allegations in paragraph 17 of the SAC.

18. BIPI admits that it holds the patent and NDA for Jardiance and markets Jardiance, in accordance with Jardiance's FDA-approved labeling. BIPI denies the remaining allegations contained in paragraph 18 of the SAC.

19. BIPI admits that Jardiance is an FDA-approved treatment for use as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. BIPI denies the remaining allegations contained in paragraph 19 of the SAC.

20. Due to the vagueness and ambiguity of the allegations contained in paragraph 20 of the SAC, BIPI is without knowledge or information sufficient to form a belief as to the truth of such allegations, and, on that basis, BIPI denies such allegations.

21. To the extent the allegation in paragraph 21 of the SAC refers to injuries other than diabetic ketoacidosis, no answer is required because, by Order dated November 21, 2017, this Court dismissed Plaintiff's claim that she developed unspecified health-related problems other than diabetic ketoacidosis. To the extent the allegation in paragraph 21 of the SAC refers to diabetic ketoacidosis, due to the vagueness and ambiguity of the allegations contained in

paragraph 21 of the SAC, BIPI is without knowledge or information sufficient to form a belief as to the truth of such allegations, and, on that basis, BIPI denies such allegations.

22. BIPI denies the allegations contained in paragraph 22 of the SAC.

23. BIPI is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 23 of the SAC, and, on that basis, BIPI denies such allegations.

24. The allegations contained in paragraph 24 of the SAC state legal conclusions to which no response is required. To the extent a response is required, BIPI denies the allegations contained in paragraph 24 of the SAC.

25. BIPI denies the allegations contained in paragraph 25 of the SAC.

26. BIPI is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 26 of the SAC, and, on that basis, BIPI denies such allegations.

27. BIPI is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 27 of the SAC related to Plaintiff's alleged use of Jardiance, and, on that basis, BIPI denies such allegations.

28. BIPI is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 28 of the SAC related to Plaintiff's alleged use of Jardiance, and, on that basis, BIPI denies such allegations.

29. BIPI is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 29 of the SAC related to Plaintiff's alleged use of Jardiance, and, on that basis, BIPI denies such allegations.

30. To the extent the allegations in paragraph 30 of the SAC refer to injuries other than diabetic ketoacidosis, no answer is required because, by Order dated November 21, 2017, this Court dismissed Plaintiff's claim that she developed unspecified health-related problems other than diabetic ketoacidosis. To the extent the allegations in paragraph 30 of the SAC refer to diabetic ketoacidosis, BIPI denies the allegations contained in paragraph 30 of the SAC.

31. BIPI is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 31 of the SAC related to Plaintiff's alleged medical history, and, on that basis, BIPI denies such allegations. BIPI denies that BIPI and/or Jardiance have in any way caused or contributed to Plaintiff's alleged injuries or damages, if any.

32. BIPI is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 32 of the SAC related to Plaintiff's alleged medical history, and, on that basis, BIPI denies such allegations. BIPI denies that BIPI and/or Jardiance have in any way caused or contributed to Plaintiff's alleged injuries or damages, if any.

33. BIPI is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 33 of the SAC related to Plaintiff's use of Jardiance, and, on that basis, BIPI denies such allegations. BIPI denies that BIPI and/or Jardiance have in any way caused or contributed to Plaintiff's alleged injuries or damages, if any.

34. The allegations contained in paragraph 34 of the SAC state legal conclusions to which no response is required. To the extent a response is required, BIPI denies the allegations contained in paragraph 34 of the SAC.

35. BIPI admits that the FDA issued a communication regarding SGLT-2 inhibitors and DKA on May 15, 2015. To the extent that the allegations in paragraph 35 of the SAC

attempt to summarize an FDA communication, BIPI states that the FDA communication speaks for itself and, on that basis, denies all remaining or inconsistent allegations in paragraph 35.

36. To the extent the allegations in paragraph 36 of the SAC are based on Jardiance's label at the time it was approved by the FDA, no answer is required because, by Order dated November 21, 2017, this Court dismissed Plaintiff's failure-to-warn claims based on Jardiance's label at the time it was approved by the FDA. To the extent a response is deemed required, BIPI lacks knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 36 of the SAC, and, on that basis, denies such allegations.

37. To the extent the allegations in paragraph 37 of the SAC are based on Jardiance's label at the time it was approved by the FDA, no answer is required because, by Order dated November 21, 2017, this Court dismissed Plaintiff's failure-to-warn claims based on Jardiance's label at the time it was approved by the FDA. To the extent an answer is deemed required, due to the vagueness and ambiguity of the allegations contained in paragraph 37 of the SAC, BIPI is without knowledge or information sufficient to form a belief as to the truth of such allegations, and, on that basis, BIPI denies such allegations.

38. BIPI admits that the FDA issued a communication regarding SGLT-2 inhibitors and DKA in December 2015. To the extent the allegations attempt to summarize an FDA communication, BIPI states that the FDA communication speaks for itself and, on that basis, denies all remaining or inconsistent allegations contained in paragraph 38 of the SAC.

39. BIPI admits that the FDA issued a communication regarding SGLT-2 inhibitors and DKA in December 2015. To the extent the allegations attempt to summarize an FDA communication or FDA action, BIPI states that the FDA communication speaks for itself and, on that basis, denies all remaining or inconsistent allegations contained in paragraph 39 of the SAC.

40. BAPI admits that the FDA issued a communication regarding SGLT-2 inhibitors and DKA in December 2015. To the extent the allegations attempt to summarize an FDA communication or FDA action, BAPI states that the FDA communication speaks for itself and, on that basis, denies all remaining or inconsistent allegations contained in paragraph 40 of the SAC.

41. To the extent that the allegations in paragraph 41 of the SAC attempt to summarize the contents of the Jardiance label before December 2015, BAPI states that the Jardiance label operative at the time of Plaintiff's alleged injury speaks for itself and, on that basis, denies the allegations in paragraph 41.

42. To the extent the allegations in paragraph 42 of the SAC are based on Jardiance's label at the time it was approved by the FDA, no answer is required because, by Order dated November 21, 2017, this Court dismissed Plaintiff's failure-to-warn claims based on Jardiance's label at the time it was approved by the FDA. To the extent a response is deemed required, BAPI lacks knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 42 of the SAC, and, therefore, denies such allegations.

43. BAPI admits that, on August 1, 2014, the FDA determined Jardiance to be safe and effective for use "as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus."

44. Due to the vagueness and ambiguity of the allegations contained in paragraph 44 of the SAC, BAPI is without knowledge or information sufficient to form a belief as to the truth of such allegations, and, on that basis, BAPI denies such allegations.

45. BAPI admits that paragraph 45 purports to quote *Wyeth v. Levine*, but denies that paragraph 45 accurately or completely describes BAPI's legal obligations. BAPI otherwise denies the allegations in paragraph 45 of the SAC.

46. BAPI admits that paragraph 46 purports to quote certain sections of the Code of Federal Regulations and the Federal Register, but denies that paragraph 46 accurately or completely describes BAPI's legal obligations. BAPI otherwise denies the allegations in paragraph 46 of the SAC.

47. To the extent the allegation in paragraph 47 of the SAC is based on Jardiance's label at the time it was approved by the FDA, no answer is required because, by Order dated November 21, 2017, this Court dismissed Plaintiff's failure-to-warn claims based on Jardiance's label at the time it was approved by the FDA. To the extent an answer is deemed required, BAPI denies the allegations in paragraph 47 of the SAC.

48. Due to the vagueness and ambiguity of the allegations contained in paragraph 48 of the SAC, BAPI is without knowledge or information sufficient to form a belief as to the truth of such allegations, and, on that basis, BAPI denies such allegations.

49. BAPI denies the allegations in paragraph 49.

50. To the extent the allegations in paragraph 50 of the SAC are based on Jardiance's label at the time it was approved by the FDA, no answer is required because, by Order dated November 21, 2017, this Court dismissed Plaintiff's failure-to-warn claims based on Jardiance's label at the time it was approved by the FDA. To the extent an answer is deemed required, due to the vagueness and ambiguity of the allegations contained in paragraph 50 of the SAC, BAPI is without knowledge or information sufficient to form a belief as to the truth of such allegations, and, on that basis, BAPI denies such allegations.

51. To the extent the allegation in paragraph 51 of the SAC is based on Jardiance's label at the time it was approved by the FDA, no answer is required because, by Order dated November 21, 2017, this Court dismissed Plaintiff's failure-to-warn claims based on Jardiance's

label at the time it was approved by the FDA. To the extent an answer is deemed required, due to the vagueness and ambiguity of the allegations contained in paragraph 51 of the SAC, BIPI is without knowledge or information sufficient to form a belief as to the truth of such allegations, and, on that basis, BIPI denies such allegations.

52. To the extent the allegations in paragraph 52 of the SAC are based on Jardiance's label at the time it was approved by the FDA, no answer is required because, by Order dated November 21, 2017, this Court dismissed Plaintiff's failure-to-warn claims based on Jardiance's label at the time it was approved by the FDA. To the extent an answer is deemed required, due to the vagueness and ambiguity of the allegations contained in paragraph 52 of the SAC, BIPI is without knowledge or information sufficient to form a belief as to the truth of such allegations, and, on that basis, BIPI denies such allegations.

53. To the extent the allegations in paragraph 53 of the SAC are based on Jardiance's label at the time it was approved by the FDA, no answer is required because, by Order dated November 21, 2017, this Court dismissed Plaintiff's failure-to-warn claims based on Jardiance's label at the time it was approved by the FDA. To the extent an answer is deemed required, BIPI denies the allegations in paragraph 53 of the SAC.

54. BIPI denies the allegations in paragraph 54 of the SAC.

55. To the extent the allegation in paragraph 55 of the SAC is based on Jardiance's label at the time it was approved by the FDA, no answer is required because, by Order dated November 21, 2017, this Court dismissed Plaintiff's failure-to-warn claims based on Jardiance's label at the time it was approved by the FDA. To the extent an answer is deemed required, BIPI denies the allegations in paragraph 55 of the SAC.

56. To the extent the allegation in paragraph 56 of the SAC is based on Jardiance's label at the time it was approved by the FDA, no answer is required because, by Order dated November 21, 2017, this Court dismissed Plaintiff's failure-to-warn claims based on Jardiance's label at the time it was approved by the FDA. To the extent an answer is deemed required, due to the vagueness and ambiguity of the remaining allegations contained in paragraph 56 of the SAC, BIPI is without knowledge or information sufficient to form a belief as to the truth of such allegations, and, on that basis, BIPI denies such allegations.

57. Due to the vagueness and ambiguity of the allegations contained in paragraph 57 of the SAC, BIPI is without knowledge or information sufficient to form a belief as to the truth of such allegations, and, on that basis, BIPI denies such allegations.

58. BIPI admits the existence of the publications contained in paragraph 58 of the SAC, including subparagraphs (a)-(f). BIPI denies that Plaintiff accurately or completely describes the published literature cited in paragraph 58 of the SAC, including subparagraphs (a)-(f).

59. The allegations contained in paragraph 59 of the SAC state legal conclusions to which no response is required. To the extent a response is required, BIPI is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 59 of the SAC, and, on that basis, BIPI denies such allegations. BIPI denies that BIPI and/or Jardiance have in any way caused or contributed to Plaintiff's alleged injuries or damages, if any, and that Plaintiff is entitled to any of the damages or relief sought against BIPI.

60. The allegations contained in paragraph 60 of the SAC state legal conclusions to which no response is required. To the extent a response is required, BIPI denies the allegations contained in paragraph 60 of the SAC. BIPI denies that BIPI and/or Jardiance have in any way

caused or contributed to Plaintiff's alleged injuries or damages, if any, and that Plaintiff is entitled to any of the damages or relief sought against BIPI.

61. BIPI denies the allegations contained in paragraph 61 of the SAC.

62. The allegations contained in paragraph 62 of the SAC state legal conclusions to which no response is required. To the extent a response is required, BIPI is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 62 of the SAC, and, on that basis, BIPI denies such allegations. BIPI denies that BIPI and/or Jardiance have in any way caused or contributed to Plaintiff's alleged injuries or damages, if any, and that Plaintiff is entitled to any of the damages or relief sought against BIPI.

63. BIPI denies the allegations contained in paragraph 63 of the SAC.

64. The allegations contained in paragraph 64 of the SAC state legal conclusions to which no response is required. To the extent a response is required, BIPI is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 64 of the SAC, and, on that basis, BIPI denies such allegations. BIPI denies that BIPI and/or Jardiance have in any way caused or contributed to Plaintiff's alleged injuries or damages, if any, and that Plaintiff is entitled to any of the damages or relief sought against BIPI.

65. BIPI denies the allegations contained in paragraph 65 of the SAC.

66. To the extent the allegations contained in paragraph 66, including subparagraphs (a)-(c), relate to products other than Jardiance, BIPI is without knowledge or information sufficient to form a belief as to the truth of such allegations, and, on that basis, BIPI denies such allegations. To the extent that any allegations contained in paragraph 66, including subparagraphs (a)-(c), relate to Jardiance, BIPI states that the mechanism of action outlined in

the Jardiance product labeling operative at the time of Plaintiff's alleged injury speaks for itself and, on that basis, denies the allegations in paragraph 66, including subparagraphs (a)-(c).

67. To the extent the allegation in paragraph 67 of the SAC is based on Jardiance's label at the time it was approved by the FDA, no answer is required because, by Order dated November 21, 2017, this Court dismissed Plaintiff's failure-to-warn claims based on Jardiance's label at the time it was approved by the FDA. To the extent an answer is deemed required, BIPI otherwise denies the allegations in paragraph 67 of the SAC.

68. BIPI denies the allegations in paragraph 68, including subparagraphs (a) – (d).

69. BIPI lacks knowledge or information sufficient to form a belief as to the truth of the allegations, and, therefore, denies the allegations in paragraph 69 of the SAC. BIPI denies that BIPI and/or Jardiance have in any way caused or contributed to Plaintiff's alleged injuries or damages, if any.

**COUNT I**  
**PRODUCTS LIABILITY – BREACH OF OR FAILURE TO DISCHARGE A DUTY TO  
WARN - STRICT LIABILITY (under Tenn. Code § 29-28-102(6))**

70. BIPI hereby incorporates all preceding responses to paragraphs 1 through 69 of the SAC as if fully set forth herein.

71. BIPI admits that it holds the patent and NDA for Jardiance and markets Jardiance, in accordance with Jardiance's FDA-approved labeling. BIPI denies the remaining allegations contained in paragraph 71 of the SAC.

72. The allegations contained in paragraph 72 of the SAC state legal conclusions to which no response is required. To the extent a response is required, due to the vagueness and ambiguity of the allegations contained in paragraph 72 of the SAC, BIPI is without knowledge or information sufficient to form a belief as to the truth of such allegations, and, on that basis, BIPI denies such allegations. BIPI denies that BIPI and/or Jardiance have in any way caused or

contributed to Plaintiff's alleged injuries or damages, if any, and denies that Plaintiff is entitled to any of the damages or relief sought against BIPI.

73. BIPI is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 73 of the SAC, and, on that basis, BIPI denies such allegations.

74. To the extent the allegations in paragraph 74 of the SAC are based on Jardiance's label at the time it was approved by the FDA, no answer is required because, by Order dated November 21, 2017, this Court dismissed Plaintiff's failure-to-warn claims based on Jardiance's label at the time it was approved by the FDA. To the extent an answer is deemed required, BIPI otherwise denies the allegations in paragraph 74 of the SAC.

75. BIPI denies the allegations in paragraph 75 of the SAC.

76. BIPI is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 76 related to Plaintiff's use of Jardiance and to Plaintiff's medical history, and, on that basis, denies the allegations in paragraph 76.

77. The allegations contained in paragraph 77 of the SAC state legal conclusions to which no response is required. To the extent a response is required, due to the vagueness and ambiguity of the allegations contained in paragraph 77 of the SAC, BIPI is without knowledge or information sufficient to form a belief as to the truth of such allegations, and, on that basis, BIPI denies such allegations.

78. BIPI denies the allegations contained in paragraph 78 of the SAC.

79. The allegations contained in paragraph 79 of the SAC state legal conclusions to which no response is required. To the extent a response is required, BIPI denies the allegations contained in paragraph 79 of the SAC.

80. The allegations contained in paragraph 80 of the SAC state legal conclusions to which no response is required. To the extent a response is required, BIPI denies the allegations contained in paragraph 80 of the SAC.

81. The allegations contained in paragraph 81 of the SAC state legal conclusions to which no response is required. To the extent a response is required, BIPI is without knowledge or information sufficient to form a belief as to the truth of such allegations, and, on that basis, BIPI denies such allegations.

82. To BIPI denies the allegations in paragraph 82 of the SAC.

83. BIPI denies the allegations in paragraph 83 of the SAC.

84. BIPI denies the allegations contained in paragraph 84 of the SAC.

85. BIPI denies the allegations contained in paragraph 85, including subparagraphs (a) – (g).

86. BIPI denies the allegations contained in paragraph 86 of the SAC.

87. BIPI denies the allegations contained in paragraph 87 of the SAC.

88. BIPI lacks knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 88 of the SAC, and, therefore, denies such allegations. BIPI denies that BIPI and/or Jardiance have in any way caused or contributed to Plaintiff's alleged injuries or damages, if any, and denies that Plaintiff is entitled to any of the damages or relief sought against BIPI.

89. BIPI denies the allegations in paragraph 89 of the SAC and specifically denies that BIPI and/or Jardiance have in any way caused or contributed to Plaintiffs' alleged injuries or damages, if any.

90. To the extent the allegation in paragraph 90 of the SAC refers to injuries other than diabetic ketoacidosis, no answer is required because, by Order dated November 21, 2017, this Court dismissed Plaintiff's claim that she developed unspecified health-related problems other than diabetic ketoacidosis. To the extent the allegation in paragraph 90 of the SAC refers to diabetic ketoacidosis, BIPI is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 90 of the SAC, and, on that basis, BIPI denies such allegations. BIPI denies that BIPI and/or Jardiance have in any way caused or contributed to Plaintiff's alleged injuries or damages, if any.

91. To the extent the allegation in paragraph 91 of the SAC refers to injuries other than diabetic ketoacidosis, no answer is required because, by Order dated November 21, 2017, this Court dismissed Plaintiff's claim that she developed unspecified health-related problems other than diabetic ketoacidosis. To the extent a response is required, BIPI is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 91 of the SAC, and, on that basis, BIPI denies such allegations. BIPI denies that BIPI and/or Jardiance have in any way caused or contributed to Plaintiff's alleged injuries or damages, if any.

BIPI denies that BIPI and/or Jardiance have in any way caused or contributed to Plaintiff's alleged injuries or damages, if any, and denies that Plaintiff is entitled to any of the damages or relief sought against BIPI.

**COUNT II**  
**NEGLIGENCE (under Tenn. Code § 29-28-102(6))**

92. BIPI hereby incorporates all preceding responses to paragraphs 1 through 91 of the SAC as if fully set forth herein.

93. The allegations contained in paragraph 93 of the SAC state legal conclusions to which no response is required. To the extent a response is required, BIPI admits that FDA

approved Jardiance as safe and effective for use “as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus,” and, at certain times not specified in the SAC, BIPI marketed Jardiance in accordance with its FDA-approved labeling. BIPI denies the remaining allegations contained in paragraph 93 of the SAC.

94. The allegations contained in paragraph 94 of the Complaint state legal conclusions to which no response is required. To the extent a response is required, BIPI denies the allegations contained in paragraph 94 of the SAC.

95. The allegations contained in paragraph 95 of the Complaint state legal conclusions to which no response is required. To the extent a response is required, BIPI denies the allegations contained in paragraph 95 of the SAC.

96. The allegations contained in paragraph 96 of the Complaint state legal conclusions to which no response is required. To the extent a response is required, BIPI denies the allegations contained in paragraph 96 of the SAC.

97. The allegations contained in paragraph 97 of the Complaint state legal conclusions to which no response is required. To the extent a response is required, BIPI denies the allegations contained in paragraph 97 of the SAC.

98. The allegations contained in paragraph 98 of the Complaint state legal conclusions to which no response is required. To the extent a response is required, BIPI denies the allegations contained in paragraph 98 of the SAC.

99. The allegations contained in paragraph 99 of the Complaint state legal conclusions to which no response is required. To the extent a response is required, BIPI denies the allegations contained in paragraph 99 of the SAC.

100. To the extent the allegations in paragraph 100 of the SAC refer to injuries other than diabetic ketoacidosis, no answer is required because, by Order dated November 21, 2017, this Court dismissed Plaintiff's claim that she developed unspecified health-related problems other than diabetic ketoacidosis. To the extent the allegations in paragraph 100 of the SAC refer to diabetic ketoacidosis, BIPI denies such allegations.

101. The allegations contained in paragraph 101 of the Complaint state legal conclusions to which no response is required. To the extent a response is required, BIPI denies the allegations contained in paragraph 101 of the SAC.

102. BIPI denies the allegations in paragraph 102, including subparagraphs (a)-(i).

103. The allegations contained in paragraph 103 of the SAC state legal conclusions to which no response is required. To the extent a response is required, BIPI denies the allegations contained in paragraph 103 of the SAC.

104. The allegations contained in paragraph 104 of the SAC state legal conclusions to which no response is required. To the extent a response is required, BIPI denies the allegations contained in paragraph 104 of the SAC.

105. BIPI lacks knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 105, and, therefore, denies such allegations. BIPI denies that BIPI and/or Jardiance have in any way caused or contributed to Plaintiff's alleged injuries or damages, if any.

106. The allegations contained in paragraph 106 of the SAC state legal conclusions to which no response is required. To the extent a response is required, BIPI denies the allegations contained in paragraph 106 of the SAC. BIPI denies that BIPI and/or Jardiance have in any way caused or contributed to Plaintiff's alleged injuries or damages, if any.

107. BAPI denies the allegations in paragraph 107 of the SAC.

108. The allegations contained in paragraph 108 of the SAC state legal conclusions to which no response is required. To the extent a response is required, BAPI lacks knowledge or information sufficient to form a belief as to the truth of the allegations, and, therefore, denies the allegations in paragraph 108 of the SAC.

109. BAPI denies the allegations in paragraph 109 of the SAC.

110. The allegations contained in paragraph 110 of the SAC state legal conclusions to which no response is required. To the extent a response is required, BAPI lacks knowledge or information sufficient to form a belief as to the truth of the allegations, and, therefore, denies the allegations in paragraph 110 of the SAC.

111. BAPI denies the allegations contained in paragraph 111 of the SAC.

112. The allegations contained in paragraph 112 of the SAC state legal conclusions to which no response is required. To the extent a response is required, BAPI lacks knowledge or information sufficient to form a belief as to the truth of the allegations, and, on that basis, denies the allegations in paragraph 112 of the SAC.

113. The allegations contained in paragraph 113 of the SAC state legal conclusions to which no response is required. To the extent a response is required, BAPI denies the allegations in paragraph 113 of the SAC.

114. To the extent the allegation in paragraph 114 of the SAC refers to injuries other than diabetic ketoacidosis, no answer is required because, by Order dated November 21, 2017, this Court dismissed Plaintiff's claim that she developed unspecified health-related problems other than diabetic ketoacidosis. To the extent the allegations in paragraph 114 of the SAC refers to diabetic ketoacidosis, BAPI is without knowledge or information sufficient to form a

belief as to the truth of the allegations contained in paragraph 114 of the SAC, and, on that basis, BIPI denies such allegations. BIPI denies that BIPI and/or Jardiance have in any way caused or contributed to Plaintiffs' alleged injuries or damages, if any.

115. To the extent the allegation in paragraph 115 of the SAC refers to injuries other than diabetic ketoacidosis, no answer is required because, by Order dated November 21, 2017, this Court dismissed Plaintiff's claim that she developed unspecified health-related problems other than diabetic ketoacidosis. To the extent a response is required, BIPI is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 115 of the SAC, and, on that basis, BIPI denies such allegations. BIPI denies that BIPI and/or Jardiance have in any way caused or contributed to Plaintiffs' alleged injuries or damages, if any.

BIPI denies that BIPI and/or Jardiance have in any way caused or contributed to Plaintiff's alleged injuries or damages, if any, and denies that Plaintiff is entitled to any of the damages or relief sought against BIPI.

#### **BIPI'S DEFENSES AND AFFIRMATIVE DEFENSES**

BIPI reserves the right to rely upon any of the following or any additional defenses and affirmative defenses to each claim for relief asserted by Plaintiff to the extent that such defenses are supported by information developed through discovery or by evidence at trial.

#### **FIRST DEFENSE**

Plaintiff's SAC, and each and every cause of action contained therein, fails to state a cause or action or claim upon which relief can be granted.

#### **SECOND DEFENSE**

Plaintiff and/or Plaintiff's prescribing physician(s) did not detrimentally rely on any labeling, warnings, or other information allegedly provided by BIPI related to Jardiance.

**THIRD DEFENSE**

The injuries, damages, and losses alleged in the SAC, none being admitted, were caused in whole or in part by the actions of the Plaintiff and/or others, over whom BIPI exercised no control, had no opportunity to anticipate or right to control, and or with whom BIPI had no legal relationship by which liability could be attributed to it because of the actions of the Plaintiff and/or others, which, by comparison were far greater than any conduct alleged as to BIPI. Any conduct on the part of BIPI allegedly causing Plaintiff's alleged injuries was not a substantial cause or factor of actual injury or damage, if any.

**FOURTH DEFENSE**

To the extent that discovery may show, Plaintiff's claims for relief may be barred in whole or in part by the applicable statutes of limitations and/or repose.

**FIFTH DEFENSE**

If Plaintiff sustained injuries or losses as alleged in the SAC, such injuries or losses may have been caused by an individual, idiosyncratic reaction or may have resulted from Plaintiff's pre-existing and/or unrelated medical, genetic and/or environmental conditions, diseases, or illnesses, subsequent medical conditions or natural courses of conditions for which BIPI is not legally responsible.

**SIXTH DEFENSE**

Plaintiff's claims are barred because Jardiance was neither defective nor unreasonably dangerous in its design, manufacture or marketing and was reasonably safe and reasonably fit for its intended use. The warnings and instructions accompanying Jardiance at the time of the occurrence of the injuries alleged by Plaintiff were legally adequate warnings and instructions.

**SEVENTH DEFENSE**

Plaintiff's claims predicated on state tort law and alleging that Jardiance was unreasonably dangerous and/or defective are barred, in whole or in part, by the doctrine of federal preemption and the Supremacy clause of the United States Constitution, Article IV, clause 2. Plaintiff's claims are preempted by federal law in that Jardiance was approved by the FDA.

**EIGHTH DEFENSE**

Some or all of Plaintiff's claims are barred by the doctrines concerning unavoidably unsafe products, including, but not limited to, the operation of comments j and k to Section 402A of the RESTATEMENT (SECOND) OF TORTS and/or barred by the RESTATEMENT (THIRD) OF TORTS.

**NINTH DEFENSE**

Plaintiff's alleged injuries and/or damages, if any, may be barred in whole or in part to the extent they were caused, or contributed to, by their own negligence, intentional conduct, consent, or by express or implied assumption of all risks.

**TENTH DEFENSE**

Plaintiff's claims may be barred, in whole or in part, by the doctrine of informed consent, to the extent Plaintiff was informed of the risks associated with treatment and willingly consented to treatment despite those risks.

**ELEVENTH DEFENSE**

Plaintiff's SAC fails to state a claim upon which relief can be granted because Jardiance was designed, manufactured and labeled in a manner that complied with the state of scientific and medical knowledge at the time of its design, testing, manufacture, distribution, marketing, and sale.

**TWELFTH DEFENSE**

At all relevant times during which Jardiance was manufactured and sold, it was reasonably safe and reasonably fit for its intended use, was not defective or unreasonably dangerous, and was accompanied by proper warnings, information, and instructions, all pursuant to generally recognized prevailing industry standards, the state of the art in existence at the time, and the state of scientific knowledge in existence at the time.

**THIRTEENTH DEFENSE**

Plaintiff's claims are barred because the benefits of Jardiance outweigh any risk involved in using the medication.

**FOURTEENTH DEFENSE**

BIPI's conduct, as well as Jardiance, fully complied with the Federal Food, Drug and Cosmetic Act and all applicable product safety requirements promulgated by the FDA. Plaintiff's claims are barred because Jardiance complied with all federal, state, and administrative regulations and applicable industry standards at all relevant times alleged in the SAC.

**FIFTEENTH DEFENSE**

Plaintiff fails to state a claim upon which relief can be granted because manufacturers and distributors of prescription drugs such as Jardiance have no legal duty to warn the patient, as opposed to the patient's physician, of risks inherent in the use of a prescription drug. At all relevant times herein, Plaintiff's prescribing physicians were in the position of learned intermediaries and/or sophisticated purchasers, and were fully knowledgeable and informed of the risks and benefits of Jardiance. Plaintiff's claims are therefore barred by virtue of the intervention of a learned intermediary or intermediaries to whom BIPI discharged its duties to

warn. Plaintiff's claims are also barred by the Sophisticated User Doctrine or similar applicable laws.

**SIXTEENTH DEFENSE**

Plaintiff's product liability cause of action is barred because, at the time Jardiance left BIPI's control, a practical and technically feasible alternative design or formulation was not available that would have prevented Plaintiff's alleged injuries and/or damages without substantially impairing the usefulness or intended purpose of Jardiance.

**SEVENTEENTH DEFENSE**

Plaintiff's claims may be barred to the extent the Jardiance that Plaintiff allegedly ingested was substantially modified and/or altered.

**EIGHTEENTH DEFENSE**

Plaintiff's claims are barred, in whole or in part, because the commercial speech of BIPI relating to Jardiance is protected under the First Amendment of the United States Constitution and the Constitution of the State of Tennessee.

**NINETEENTH DEFENSE**

Plaintiff's claims may be barred in whole or in part by the doctrines of waiver, estoppel, and laches.

**TWENTIETH DEFENSE**

To the extent Plaintiff's claims are based on alleged misrepresentations made to FDA, such claims are barred pursuant to *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001).

**TWENTY-FIRST DEFENSE**

Plaintiff's claims are barred and/or this Court should defer this matter, in whole or in part, pursuant to the doctrine of primary jurisdiction, in that the FDA is charged under the law with regulating prescription drugs, including Jardiance, and is specifically charged with determining the content of the warnings and labeling for prescription drugs.

**TWENTY-SECOND DEFENSE**

Plaintiff's claims are barred by a lack of privity between Plaintiff and BIPI, because BIPI did not sell or distribute Jardiance directly to Plaintiff.

**TWENTY-THIRD DEFENSE**

BIPI is entitled to, and claims the benefit of, all defenses and presumptions set forth in or arising from any rule of law or statute in the State of Tennessee and any other state whose law is deemed to apply in this case, including but not limited to any and all defenses and presumptions which are or may be available to it pursuant to the Tennessee Product Liability Act, Tenn. Code Ann. § 29-28-101, *et seq.*

**TWENTY-FOURTH DEFENSE**

BIPI affirmatively pleads any and all defenses which are or may be available to it pursuant to the Uniform Commercial Code as adopted in Tennessee.

**TWENTY-FIFTH DEFENSE**

In the unlikely event that BIPI is found liable to Plaintiff, BIPI is entitled to a credit or offset for any and all sums that Plaintiff has received or may hereafter receive by way of any and all settlements arising from Plaintiff's claims and causes of action. BIPI alternatively asserts its right to a proportionate reduction of any damages based on comparative fault or the percentage of negligence attributable to Plaintiffs or to any settling tortfeasor under Tennessee law and/or

the laws of any other State or Commonwealth of the United States whose laws might be deemed controlling in this case. Thus, BIPI's liability, if any, is limited to its percentage of responsibility for the injuries of Plaintiff, if any, regardless of whether or not other persons or entities are named as co-defendants. Further, any verdict or judgment rendered against BIPI must be reduced by those amounts that have been, or will, with reasonable certainty, replace or indemnify Plaintiff, in whole or in part, for any past or future claimed economic loss, from any collateral source such as insurance, social security, worker's compensation, or employee benefit programs. To the extent Plaintiff is seeking recovery for the benefits entitled to be received or actually received from any other source for injuries alleged in the SAC, such benefits are not recoverable in this action under Tennessee law or any other applicable law.

**TWENTY-SIXTH DEFENSE**

Plaintiff's claims are barred in whole or in part by the applicable provisions of the United States Constitution, the Tennessee Constitution, should it apply, and/or the applicable Constitution of any other State or Commonwealth of the United States whose laws might be deemed controlling in this case.

**TWENTY-SEVENTH DEFENSE**

BIPI asserts that choice of law rules should determine which jurisdiction's laws govern this case, and expressly reserves the right to supplement this answer with any defenses that may be available to it under the law of the jurisdictions determined to apply to it in accordance with choice of law rules.

**TWENTY-EIGHTH DEFENSE**

If Plaintiff was injured by Jardiance, those injuries occurred because the product was used for a purpose other than that for which it was intended, in a manner other than that in which

it was intended to be used, and in disregard of instructions and directions regarding its use. Such misuse was not reasonably foreseeable to BIPI.

**TWENTY-NINTH DEFENSE**

If Plaintiff sustained damages as alleged in the SAC, which is denied, Plaintiff has failed to mitigate their damages and any recovery is to be diminished by the degree of said failure to mitigate.

**THIRTIETH DEFENSE**

BIPI denies, to the extent the actions alleged may have occurred, that any entity engaging in the activities alleged was acting as the agent or servant of BIPI, or at the instruction or subject to the control of BIPI with regard to any of the actions described in the Complaint; thus, BIPI is not liable for any acts or omissions of such third parties as a matter of law. Plaintiff's recovery, if any, therefore is barred or should be reduced and/or apportioned in accordance with applicable Tennessee law.

**THIRTY-FIRST DEFENSE**

Plaintiff's claims are barred, in whole or in part, because any injuries and damages alleged by Plaintiffs were the direct and proximate result of an operation of nature, or an act of God, or other independent, unforeseeable, superseding, or intervening cause.

**THIRTY-SECOND DEFENSE**

Plaintiff is barred from recovery to the extent she failed to maintain or preserve evidence.

**THIRTY-THIRD DEFENSE**

Plaintiff did not suffer any actual injury, loss, or damages because of the alleged use of Jardiance.

**THIRTY-FOURTH DEFENSE**

Plaintiff's claims may be barred, in whole or in part, to the extent that Plaintiff lacks standing.

**THIRTY-FIFTH DEFENSE**

Any dangers associated with the use of the prescription drugs that may have caused Plaintiff's alleged injuries, if any, were open and obvious, and Plaintiff is therefore barred from recovery.

**THIRTY-SIXTH DEFENSE**

Plaintiff's claims are barred by the doctrine of accord and satisfaction and/or release.

**THIRTY-SEVENTH DEFENSE**

All or some of Plaintiff's claims for damages have not accrued and are too speculative, uncertain, and contingent to be recoverable.

**THIRTY-EIGHTH DEFENSE**

The claims against BIPi are barred by Sections 2, 4, 6(c), and 6(d) of the Restatement (Third) of Torts: Products Liability.

**THIRTY-NINTH DEFENSE**

Plaintiff's alleged causes of action are barred, in whole or in part, by lack of defect under either the prudent manufacturer test or the consumer expectations test.

**FORTIETH DEFENSE**

Plaintiff's Complaint and each cause of action are barred by the doctrine of immunity for prescription drugs and medical devices, by the Commerce Clause, Article I, Section 8, of the Constitution of the United States as an undue burden upon interstate commerce and/or by the preemption doctrine in that Plaintiffs have asserted claims for relief which, if granted, would

constitute an impermissible burden by this Court of federal laws, regulations, and policy related to the development and marketing of prescription drugs and medical devices in violation of the Supremacy Clause, Article IV, Clause 2 of the Constitution of the United States.

**FORTY-FIRST DEFENSE**

The fault of Plaintiff (including negligence, assumption of risk, incurred risk and failure to mitigate) may be greater than fifty percent (50%) of the total fault causing the alleged damages to Plaintiff, and therefore, Plaintiff may be barred from any recovery in this action.

**FORTY-SECOND DEFENSE**

To the extent that BIPI failed to answer any allegation against it, BIPI denies such allegations.

**FORTY-THIRD DEFENSE**

BIPI hereby gives notice that it intends to rely upon such other defenses and affirmative defense as may become available or appear during the course of discovery proceedings in this case and hereby reserves the right to amend this Answer to assert such defenses and affirmative defenses.

**JURY DEMAND**

BIPI demands a trial by jury on all issues so triable.

**PRAYER FOR RELIEF**

BIPI denies that Plaintiff is entitled to recover any relief requested in Plaintiff's Prayer, or any relief whatsoever.

WHEREFORE, BIPI prays for judgment as follows:

1. That Plaintiff takes nothing by the SAC;

2. That the Court enter judgment dismissing the SAC against BIPI, with prejudice;
3. That the Court award BIPI its reasonable expenses and costs incurred in the defense of the SAC;
4. That the Court grant BIPI such relief as the Court may deem proper.

**Dated:** December 5, 2017

Respectfully submitted,

By: s/ Clarence A. Wilbon

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*Attorneys for Defendant Boehringer  
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**CERTIFICATE OF SERVICE**

I hereby certify that on this day, December 5, 2017, a true and correct copy of the foregoing was filed via the Court's Electronic Case Filing System. Notice of this filing will be sent to all parties indicated on the electronic case filing receipt. Parties may also access this filing through the Court's ECF system.

s/ Clarence A. Wilbon